

Contamac Ltd.

Special 510(k): Manufacturing Process Change, Premarket Notification

SPECIAL 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

K062548

NOV 1 2006

Applicant information:

Date Prepared: August 28th, 2006

Submittals Name: **CONTAMAC Ltd.**
Bearwalden Business Park
Saffron Walden
Essex United Kingdom CB11 4JX

Contact Person:

Medvice Consulting, Inc.
Martin Dalsing, Consultant and U.S. Agent for Contamac Ltd.
2214 Sanford Drive, B7
Grand Junction, CO 81505
(970) 243-5490
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Device Information:

Device Classification: Class II

Classification Number: HQD

Classification Name: Daily Wear Rigid Gas Permeable (RGP) Contact Lens

Trade Name: **OPTIMUM GP (Oxygen Permeable) Daily Wear Contact Lenses**

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Device Description:

The **OPTIMUM GP** series of contact lenses are fabricated from the hydrophobic contact lens materials (roflufocon A), (roflufocon B), (roflufocon C), (roflufocon D), & (roflufocon E). When placed on the human cornea, the OPTIMUM GP rigid gas permeable contact lenses act as a refracting medium to focus light rays upon the retina.

OPTIMUM GP Contact Lens for Daily Wear is available with a plasma surface treatment. Lenses are packaged non-sterile and shipped in one of the following GP solutions.

Solution	Manufacturer
Boston Simplus	Bausch & Lomb
Unique Ph	Alcon
Optimum CDS	Lobob Laboratories

The **OPTIMUM GP** Contact Lens for Daily Wear are available as lathe cut contact lenses with spherical, aspheric, bifocal, multifocal or toric anterior and/or posterior designs in clear and tinted versions.

The **OPTIMUM GP** Contact Lens for Daily Wear is a rigid gas permeable methacrylate copolymer of Methyl methacrylate, 1,1,1,3,3,3 - Hexafluoroisopropyl Methacrylate, Methacryloxypropyl Tris(trimethylsiloxy) silane, 1,3-bis(methacryloxypropyl)-1,1,3,3-tetrakis(trimethyl siloxy)disiloxane, 2-Hydroxyethyl Methacrylate, and Methacrylic acrylic acid cross-linked with Ethylene Glycol Dimethacrylate.

The **OPTIMUM GP** Contact Lens for Daily Wear incorporates a visibility tint to make the lens more visible for handling. The tinted lenses contain one or more of the following color additives: D&C Green No.6, C.I. Solvent yellow No. 18, and FD&C Red No. 17.

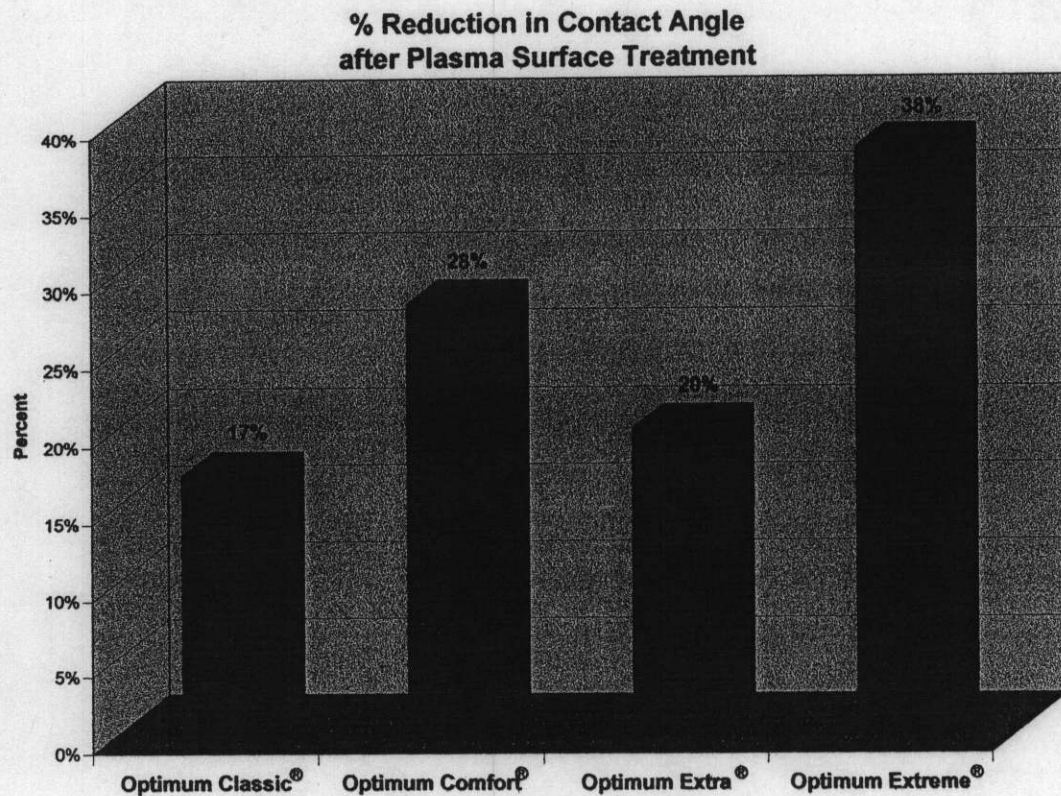
UV Blocker

In the **OPTIMUM GP** Contact Lens with UV Blocker, a Benzophenone UV blocker is used to block UV radiation. The UV Blocker is 2,2'-Dihydroxy-4,4'-dimethoxybenzophenone. The UV blocking for OPTIMUM GP averages > 98% in the UVB range of 280nm – 315nm and 95% in the UVA range of 316 – 380nm.

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The following chart depicts the dramatic reduction in the **OPTIMUM GP** contact lens wetting angle measurements post plasma surface treatment.



Unmodified Predicate Devices:

The **OPTIMUM GP (Oxygen Permeable) Daily Wear Contact Lenses** is substantially equivalent to Contamac Ltd. own unmodified predicate devices:

1. **Optimum GP (rofluvocon) K033594**, Contamac Ltd.

INDICATIONS FOR USE:

The **OPTIMUM GP** (rofluvocon A, rofluvocon B, rofluvocon C, rofluvocon D, and rofluvocon E) Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.

The lens may be disinfected with a chemical disinfection system only.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

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Technological Characteristics Comparison:

Technological Characteristic / Device	Optimum GP (roflucocon) Gas Permeable Contact Lens. Modified Device	Optimum GP (roflucocon) Gas Permeable Contact Lens. Un-Modified Device K033594
Intended Use	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.
Functionality	After machining from the optical blank, the contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	After machining from the optical blank, the contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.
Indication for Use	Daily wear, Rigid Gas Permeable RGP Contact Lens	Daily wear, Rigid Gas Permeable RGP Contact Lens
Production Method	Lathe-cut	Lathe-cut
FDA Group #	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate
USAN name	roflucocon	roflucocon
Water Content	<1%	<1%
Surface characteristic	hydrophobic	hydrophobic



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 1 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Contamac Ltd.
c/o Mr. Martin Dalsing
Medvice Consulting, Inc.
Official Correspondent/Consultant and US Agent for Contamac Ltd.
2214 Sanford Dr. Ste. B7
Grand Junction, CO 81505

Re: K062548

Trade/Device Name: OPTIMUM GP (rofluvocon A, rofluvocon B, rofluvocon C,
rofluvocon D and rofluvocon E) Daily Wear Contact Lens

Regulation Number: 21 CFR 886.5916

Regulation Name: Rigid gas permeable contact lenses

Regulatory Class: Class II

Product Code: HQD

Dated: October 19, 2006

Received: October 20, 2006

Dear Mr. Dalsing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

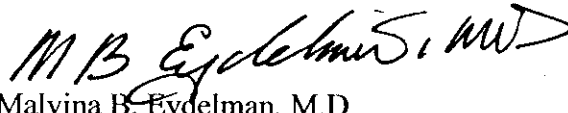
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "MB Eydelman, M.D.", with a stylized flourish at the end.

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose
and Throat Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

Device Name: OPTIMUM GP (Oxygen Permeable) Daily Wear Contact Lenses.

INDICATIONS FOR USE:

The **OPTIMUM GP** (roflufocon A, roflufocon B, roflufocon C, roflufocon D, and roflufocon E) Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.
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Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number 4062548